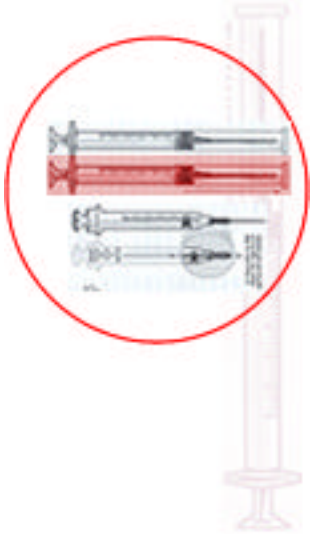
NIOSH recommends that health care facilities use safer medical devices to protect workers from needlestick and other sharps injuries. Since the passage of the Needlestick Safety and Prevention Act in 2000 and the subsequent revision of the OSHA Bloodborne Pathogen Standard, all health care facilities are required to use safer medical devices.

SAFER MEDICAL DEVICE IMPLEMENTATION IN HEALTH CARE FACILITIES

SHARING LESSONS LEARNED

NIOSH has asked a small number of health care facilities to share their experiences on how they implemented safer medical devices in their settings. These facilities have agreed to describe how each step was accomplished, and also to discuss the barriers they encountered and how they were resolved, and most importantly, lessons learned.



Phase 4 Report: Evaluate Safer Medical Device(s)

Background

Our health-care system is a nonprofit, consumer-governed system that coordinates care and coverage. It provides care to nearly 600,000 people in the Western United States. Our system includes a nationally recognized research center, charitable community foundation, medical centers, specialty centers, and hospitals. In addition, we provide home health care services to our members and skilled nursing services through our long-term care facility. We own and operate our own laboratory. We employ nearly 10,000 staff including an associated 1,050 physician group practice. There are approximately 4,500 clinical staff who use sharp devices.

Our health system has implemented five safer devices over the last eighteen months. These included a shielded IV catheter, shielded phlebotomy needle, protected disposable scalpel, safety lancet, shielded needle for disposable syringes and a self-sheathing syringe. We had previously implemented a needle-free IV system and shielded butterfly needles. This report provides a description of our organization's process to evaluate safety IV catheters. Our organization selected two safety IV catheters (supplied by different vendors) to trial with frontline staff after our pre-selection evaluation. Both catheters were re-sheathing devices.

The selection criteria our sharps injury prevention team used for site selection were volume of use, broad representation of clinical staff (e.g., inpatient, outpatient and specialty representation) and geographical distribution. A sub-committee of our sharps injury prevention team chose thirteen sites. The following sites were selected:

Region 1	Region 2	Region 3	Region 4
Specialty Center Ambulatory Treatment Center	Ambulatory Oncology Unit and Infusion Center	Hospital Urgent Care	Medical Center Infusion Room
Urgent Care	Hospital Special Care Nursery	Operating Room, Post Anesthesia Care Unit,	Medical Center Urgent Care

		Ambulatory Care Unit	
Ambulatory Surgical Unit	Hospital Obstetrics Unit	Medical/ Telemetry Unit	
	Specialty Center Endoscopy Unit	Ambulatory Infusion Center	

The staff represented at these sites included: Nurses, physicians (including anesthesiologists), and nurse anesthetists.

Training

Both vendors provided the training for correct use of the safety IV catheters. One hundred and fifty staff were trained for the first product and one hundred and forty-seven staff were trained for the second product. The departmental inservices were fifteen to thirty minutes long, depending on the number of staff attending. Anesthesia staff were trained when they came into the OR admitting area to work. After the inservices, vendor representatives were available on-site to continue to train and review the procedure for the safety device use with staff individually or in small groups. Generic flyers were given to each manager to complete and post on their units announcing the training (see attachment 1).

The chairperson of the sharps injury prevention team contacted each pilot site departmental manager to determine the best training times for each department. A schedule was developed for the vendor, which included: site location, manager name, manager phone number, number of shifts, length of shifts (to determine time of day for training), number of nurses, and training times (see attachment 2). The vendors followed up with the managers to verify training dates and times.

Description of the Process to Evaluate the IV Catheters

Each of the two IV catheters were piloted at the above thirteen sites for three weeks each. The pilot dates were consecutive. Vendor representatives brought product to each unit/department the day before their specific trial was to begin. The last day of each trial period, the vendor representatives removed their product from the unit/department. The product was stored in separate bins from the current stock. Our material management specialists determined where the bins would be located in each department. Vendors monitored the volume of product used and ensured that the safety IV catheters were

available throughout each of the pilot periods. Both the current and new safety IV catheters were available during the pilot period.

Vendor representatives were on-site all three shifts the first week in the hospital and all shifts in the outpatient departments. Over the next two weeks, the vendor representatives made periodic visits to each site to troubleshoot for each of the respective trial periods. For the hospital system, one vendor was available by pager; the other vendor was available by overhead page.

Description of the criteria and measures used in the device evaluation

The safety injury prevention team developed the criteria and measures to be used for the evaluation of the IV catheters. The IV catheter device specific form (see attachment 3) was developed using the National Institute for Occupational Safety and Health Alert *Preventing Needlestick Injuries in Health Care Settings*, DHHS (NIOSH) Publication No. 2000-108, November 1999, the Safety Feature Evaluation Form from the Training for Development of Innovative Control Technology Project and frontline staff suggestions. The questionnaire evaluated the following criteria: safety, usability, advantages and disadvantages of the product, patient discomfort, effectiveness of training, need for extensive training to use the device correctly, and a section for general comments.

The vendors handed out evaluation forms the third week of each respective pilot period. Staff either gave their evaluation forms to the manager or charge nurse or placed the form into a designated evaluation envelope. Each manager was sent a specially marked envelope with a return address label on the front to collect the evaluation forms. Most managers posted this envelope in a visible area in their units, consequently most staff placed their own evaluation forms in the envelope. At the end of each pilot period, the manager forwarded the evaluation forms to our centralized Material Management department for analysis.

Evaluation Process used to determine the effectiveness of the device and whether to continue its use

The process the sharps injury prevention team developed to determine the effectiveness of the IV catheters was that the evaluation form would be completed at the end of each three week trial or sooner, if the frontline staff had a variable schedule. This time period was

selected so staff would have enough time for multiple uses of the product. Both vendors supplied free product for the trial. The following sizes of catheters were evaluated based upon the department needs:

IV Catheter Sizes
22GA x 1"
16GA x 1-1/4"
18GA x 2"
24GA X ¾"
16GA X 2"
18GA X 1-1/4"
20GA X 1-1/4"
14GA X 2"

The chairperson and project manager of the sharps injury prevention team had weekly discussions with each vendor as to the status of the respective pilots. The chairperson, project manager and members of the sharps injury prevention team were contacts for feedback from managers and staff during the trial period. Infection Control monitored if any needlesticks occurred with the piloted safety IV catheters. There were no needlestick occurrences.

Material Management analyzed the evaluation forms. Each criterion on the form was rated on a 5-point scale; with 1 being the lowest (worst) score possible and 5 being the highest (best) score possible. In addition, each criterion was given a weight as to the importance of the feature. A 5-point scale was used; with 1 being the lowest (worst) score possible and 5 being the highest (best) score possible. The weighted score for each criterion was calculated by taking each criterion score (1 through 5) multiplied by the criteria weight score (1 through 5). All the weighted scores were added and divided by the number of criteria to calculate the total average score for each evaluation form.

- An IV Catheter product receiving an overall score in the 1 or 2 range indicates significant problems with the usefulness or usability of the product. A product with a score in this range does not meet clinical criteria for use in our organization. If all products evaluated were in this range, we would attempt to identify and evaluate additional products in the same category.

- A product receiving an overall score of 3 meets initial clinical criteria for use in our organization.

- In cases where two different products are functionally equivalent and both products score either a 4 or 5 in the pilot evaluation, the product having the lowest overall cost would be chosen for implementation. A product receiving an overall score of 4 or 5 would be selected over a product with a score of 3.

The overall weighted scores for the pilot evaluation on the two IV catheters were 2.8 (product #1) and 3.7 (product #2).
There was a 46% evaluation return rate for product #1 and 61% return rate for product #2. The average number of times per frontline staff the product was used was 9.8 for product #1 and 11.1 for product #2. Forty-eight general comments were received for product #1 and thirty-five for product #2. Based upon the established criteria and scoring guidelines, product #2 was selected for implementation.

Of interest were the scores on two of the criteria to determine patient satisfaction and the requirements for training. The criterion used for patient satisfaction was "Patient discomfort was not increased". The score for product #1 was 2.4 and 3.5 for product #2. The criterion for training requirements was "The user does not need extensive training for correct operation". The score for product #1 was 3.7 and 4.4 for product #2.

Determination whether the device was being used as planned during the pilot evaluation

The primary method our organization used to determine if the safety IV catheters were being used was to monitor the volume of stock in the storage bins where the pilot IV catheters were stocked. This was monitored by the vendors and reported to the chairperson and project manager of the sharps injury prevention team. E-mail messages and voice-mail messages were sent to department managers of units that had lower participation in use by the chairperson and project manager. Managers were requested to encourage the use of the product with their staff.

A second method utilized by some units was developing departmental champions for the products. They assisted in problem-solving and encouraging staff to use the new products.

The third method utilized to increase participation in use of the IV catheters was having the vendors on the units identify who had not been trained and then training them. The vendors also problem-solved with trained staff and encouraged the use of the catheters.

The most troublesome area was ensuring the physicians had been trained on using the products. After the initial training of staff and the pilot had begun, the vendors contacted the chief of staffs of several departments to schedule specific training for the physicians.

Changes to the process by staff

In general, the preparation and planning with the managers, vendors, material management and the sharp injury prevention team for the pilot ensured a successful trial of the IV catheters. In hindsight, physician-specific training at the sites that included physicians should be scheduled in addition to the general staff inservices.

Lessons learned during the process of evaluating IV catheters

- Planning and preparation for the pilot with managers, vendors, and material management was critical. Our pilot implementation was very smooth and successful due to this work.
- The process must provide support to the managers in organizing the training schedule, communication to staff about the pilot, and facilitating the evaluation process.
- The vendors must be experienced in facilitating a large trial and have enough representatives to train and provide problem-solving support. The vendor must be directly involved with the organization in planning the trial (e.g. start and end dates of the trial, how, what sizes, when, where product will be stocked, representative availability to problem-solve on units, and being the cheerleader to encourage staff to complete the evaluation forms).
- Material management commitment is crucial in ensuring the product will be available for the trial, establishing where the product will be stocked for the trial and assisting the vendors in stocking the product.
- Concise, frequent communication to the managers regarding the trial (see attachment 4, an example of an e-mail communication tool).
- Project manager or other designated person must coordinate the pilot process. The time involved will depend on the size of the pilot. For a large organization, an estimate of time is 10-15 hours a week (planning, coordinating, problem-solving).
- Problem solving worked best when done over the telephone or in-person rather than by e-mail.
- It was important to frontline staff to have their current IV catheters available during the trial to ensure they had products they were

familiar and comfortable with for an emergency situation or difficult IV start.

What would we do differently if we were to begin the process again

Again our process went very smoothly due to our planning with the critical team members, i.e. vendors, material management, managers, sharps injury prevention team. One area we will improve on is communication with the physicians regarding sharp safety pilots and sharp safety in general. In the future, communications will be placed in the medical staff newsletter and provide better information to the medical staff chiefs regarding sharp safety, pilot evaluations, and problem-solving avenues.

Advice to a similar facility just starting the process

<u>In general:</u>

- Be organized and have a plan.
- Ensure managers are committed to participating in the pilot. Ask them to participate, do not tell them.
- Vendor support is imperative. –The vendor must be a team player and be able to manage a pilot evaluation that fits the size of your organization.
- Have a pre-pilot product selection process that is vigorous so unsafe products are not piloted with frontline staff.

<u>Specifically:</u>

- Develop a pilot device work plan that includes:
  - Adequate resources are available to manage the pilot process (e.g. frontline staff and project manager time, cost of product [if vendor does not supply free])
  - Selection order of pilot products
  - Identification of departments or sites to participate in evaluation
    - Develop selection criteria
    - Select sites
    - Request participation from managers of selected sites
  - Obtain product and education materials for pilot evaluation
    - Ensure product will be available on start date and throughout trial
    - Establish procedure for stocking and distribution of trial product
    - Review training plan and materials
  - Implement training using device manufacturer's representatives

        - Determine length of training
        - Determine training start dates
        - Determine clinical experts-how many per site
        - Develop process for tracking and monitoring of training
    - Implementation of pilot
        - Determine start and end dates of trial for each product
        - Determine if all areas will be implemented at the same time
        - Develop a communication plan
            - Organization
            - Managers
            - Staff, e.g. flyers, posters, organizational newsletter
    - Determine Evaluation Process
        - Evaluation form development
        - Determine when the evaluation form will be completed (e.g. after how many uses, the end of the trial)
        - Determine process on how evaluation forms will be collected
        - Determine who will analyze the evaluation forms
        - Develop overall scoring measurement criteria to determine if product(s) are clinically acceptable

- Stocking the IV catheters in bins facilitated staff knowing where the new devices were and aided in determining the volume of use. It also was an easy method for the vendors to stock the units.
- Support the managers with this process as much as you can.
- Provide concise, detailed information about the trial and update the information in a timely manner. Work with the manager to determine the best days and times for training. Develop training schedule that is sent to all managers (staff from one unit may be able to attend training on another unit if needed). Provide flyers for managers to post announcing the training. Provide specially marked envelopes for collection and return of the evaluation forms.

The role of the sharps injury prevention team

The sharps injury prevention team was significant in the success of the pilot process. The committee provided oversight of the process. A sub-committee of the team was formed and developed a work plan for the pilot evaluation. This work was critical to the smooth implementation of the pilot. Having a smaller work group facilitated quick decision-making regarding the implementation steps as described in the above section. The sharps injury prevention team approved the sub-committee's workplan and decisions regarding implementation were reported to the committee. The sharps injury prevention team also provided input and approved the IV Catheter

Evaluation form. As members of the team, the chairperson, project manager, and materials management representative facilitated implementing much of the work plan.

Estimation of the costs associated with Phase 4

Type of Staff/Cost	Hours
Management	26
Administrative	160
Front-line (includes training time	100
Total	286

*Free product was provided to us by the vendors, otherwise this cost would need to be factored into the estimation of the costs.

Attachment 1

[Name of Organization]
Safety IV Catheter Trial

To reduce the risk of accidental exposure to bloodborne pathogens

Trial Dates: **Safety Product:**

Inservice Dates		
Vendor #1	Shift	Time
Vendor #2	Shift	Time

After the initial inservice training, representatives will be available on-site to continue to inservice and review with staff individually or in small groups. Inservice training is **required** before use of the new devices.

Attachment 2

[Name of Organization]

Safety IV Catheter Trial
Inservice Schedule
Trial Dates

Location	Manager	Mgr Phone #	# Shifts	Length of Shifts	# Nurses	Inservice Times/ Comments

Attachment 3

[Name of Organization]

SAFETY DEVICE EVALUATION FORM

IV Catheter

Item to be Evaluated:_____ Date Completed:_____

Department:_____ Job Title:_____

Number of times catheter used: 5 10 20 25

Glove Size: XS S M L XL

You are being asked to participate in the evaluation process of selecting a safer IV catheter. [Organization Name] is committed to reducing and preventing the risk of percutaneous injuries and blood/body fluid exposures. In addition, OSHA requires the use of safer medical devices to reduce exposure to bloodborne pathogens.

Directions

- Please circle the most appropriate answer for each question.
- Comment on the sheet any concerns that are not covered by the questionnaire.
- Return the completed sheet to your manager or charge nurse.

		☹ **Score** ☺
		disagree……agree
1.	The safety feature can be **activated** using a one handed technique	1 2 3 4 5
2.	Use of this product **requires** you to use the safety feature	1 2 3 4 5
3.	The user activated the safety device every time the device was used	1 2 3 4 5
4.	The user can tell when the safety device has been activated	1 2 3 4 5
5.	The safety feature operates reliably	1 2 3 4 5
6.	The safety feature **does not** interfere with intended use of this product	1 2 3 4 5
7.	This product **does not** require more time to use than the current device	1 2 3 4 5
8.	The device is easy to use and does not affect my ability to start IV	1 2 3 4 5
9.	The device is easy to use while wearing gloves	1 2 3 4 5
10.	Sharpness of the needle is acceptable	1 2 3 4 5
11.	Patient discomfort **is not** increased	1 2 3 4 5
12.	The device allows for rapid visualization of flashback in the catheter or chamber	1 2 3 4 5
13.	The instructions I received on how to use the device were helpful	1 2 3 4 5
14.	The user does **NOT** need extensive training for correct operation	1 2 3 4 5

Select the device you prefer:

Vendor #1_____ Vendor #2_____

NAME:_____

COMMENTS:

Attachment 4

[NAME of ORGANIZATION]
Safety IV Catheter Trial

[Date of Trial]

Thank you for agreeing to participate in the Safety IV Catheter trial. The trial will begin [DATE]. Your support regarding the importance of staff participation in selecting and evaluating safer IV Catheters and [Name of Organization] commitment to reducing and preventing the risk of percutaneous injuries and blood/body fluid exposures is very important. The following outlines the implementation plan for the trial:

Manager to Do List:

1. Arrange training time for each shift on [Dates]. Notify [designated person or department] of training dates and times.
2. Post flyers about safer IV Catheter trial on unit. Ensure staff are aware of the trial. Encourage staff to participate in the trial; staff input is very important.
3. Collect evaluation forms the 3rd week of <u>each</u> trial period and send to [designated person or department-include contact name and location].

Trial Sites: [List sites]

Trial Begin Dates:

Venor #1 [Dates]
Vendor #2 [Dates]
Each trial will be 3 weeks.

- Representatives will bring product to each unit/department the day before each trial begins. Vendor #1 will remove their product [Date] and Vendor #2 will remove their product [Date].
- The product will be stored in bins separate from current stock. Your [designee] will assess the location of where the bins will be located. Vendors will monitor volume of product used and ensure safety product is available throughout the trial.
- Both the old product and the new product will be available during the trial

Inservice Training Dates: Managers will need to arrange for training time per each shift, on the day each trial begins, if feasible. After the initial training, representatives will train staff individually or in small groups.

Inservice length is approx. 15 minutes.

For Each Trial:

- Representatives will be on-site all three shifts the first week in the hospital and all shifts in outpatient. Representatives will trouble-shoot the next two weeks of each respective trial.
- Staff must sign-in for inservices attended to document training.
- *Staff are required to be trained before use of the new products.*
- The representatives will let the manager or charge nurse know if staff are not using the IV Catheter being trialed. We need your

support to encourage staff to participate in the trial, as one of the two devices will be implemented based upon the evaluation results.

Evaluation Forms:

- **Vendors will handout evaluation forms the third week of each trial.**
- **The evaluation forms will be given to the Manager or charge nurse who will forward the forms to [designated department or person- include contact name and location], for analysis. The forms should be forwarded after each trial ends.**

Communication Plan:

- Generic Flyers to be posted on the unit/department about the new product. They will be sent to each manager the week of [Date].
- Article in [Organization Newsletter] [Date]
- E-mail updates regarding trial
- Vendor #1 representatives will have individual pagers for trouble-shooting
- Vendor #2 representatives can be overhead paged for trouble-shooting

Any questions regarding the trial, please call or e-mail [Name], [Department], at [Phone number].